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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,653	03/13/2001	Kenneth F. Buechler	071949-1314	425721
30542	7590	10/03/2003	EXAMINER	
FOLEY & LARDNER			ALEXANDER, LYLE	
P.O. BOX 80278			ART UNIT	
SAN DIEGO, CA 92138-0278			PAPER NUMBER	

1743

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/805,653

Applicant(s)

BUECHLER, KENNETH F.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 74-113 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 101-113 is/are allowed.
- 6) ☒ Claim(s) 74-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74 and 77-88 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 1-44, 1-50 and 1-15 of U.S. Patent No. 6,143,576; 6,156,270 ; 6,019,944 and 5,458,852 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a diagnostic device capable of capturing "at least one target ligand" and the use of "time gates".

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 74, 77-84, 86, 88-89, 91-93, 95 and 97-100 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sun et al. (USP 5,238,652).

See the appropriate paragraph of paper 18.

***Claim Rejections - 35 USC § 103***

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 75,85,87,90, 94 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al.

See the appropriate paragraph of paper 18.

Sun et al. teaches simultaneous detection of 5 different analytes but is silent to the claimed at least 50.

The court decided St. Regis Paper Co. v. Bemis Co., Inc. and In re Harza (124 USPQ 380) "that the mere duplication of part has no patentable significance unless a new and unexpected result is achieved". Further, it is advantageous to create a test device that can detect more than one analyte to gain the advantages of using less sample, saving time and technician labor.

It would have been within the skill of the art to further modify Sun et al. and use at least 50 different ligand test regions to gain the above advantages and in view of St. Regis Paper Co. v. Bemis Co., Inc. and In re Harza (124 USPQ 380).

***Allowable Subject Matter***

Claims 101-113 are allowed.

Claims 76 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The 7/18/03 amendments to claim 78 define over Sun et al. However, the Double Patenting issues remain. When the Double Patenting issues are resolved, this

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claim would be objected to as being dependent upon a rejected base claim as claim 76 is above.

***Response to Arguments***

Applicant's arguments with respect to claims 74-100 have been considered but were not fully convincing.

Applicant's response the 35 USC 112 issues were convincing and these rejections have been vacated.

Applicants state Sun et al. fails to teach a capillary space having a non-absorbent surface and a plurality of capture zones. Sun et al. teach in column 2 lines 48+ that at least five drugs of abuse are screen for which has been read on the claimed plurality of capture zones. The housing(201) has been read on the claimed non-absorbent surfaces because the housing is in contact with the capillary and capture zones.

Applicant's state Sun et al. teaches porous chromatographic zones. The instant claim language is open and does not exclude additional porous zones.

Applicants traverse the 35 USC 103 rejections of Sun et al. on the same grounds as above and the Office also maintains the above positions. Additionally , Applicants state the Office has improperly Applied In re Boesch because the suggestions for the modification has not come from the prior art. The Office maintains the court has decided that these matters are within the skill of the art and not ordinarily a matter of invention. The Office maintains these rejections.

Applicants state the covalent bonding of the immunogen to a particles would destroy Sun et al. because the particles are required to be free flowing. Sun et al.

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teaches binding materials specific to the analyte of interest to latex particles. The bond referenced to by the Office is that between the binding material and the latex particle.

Finally, Applicants provided 5 document without the inclusion of a PTOL-1449. To considered the submission, Applicants must comply with 37 CFR 1.98, which among other things, requires an IDS.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander  
Primary Examiner  
Art Unit 1743

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September 22, 2003